

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA and the States)
of CALIFORNIA, DELAWARE, FLORIDA,)
HAWAII, ILLINOIS, LOUISIANA,)
MASSACHUSETTS, NEVADA, NEW)
HAMPSHIRE, NEW MEXICO, TEXAS,)
TENNESSEE and VIRGINIA, and the DISTRICT)
OF COLUMBIA *EX REL.* JOSEPH)
PIACENTILE,)

)
Plaintiffs,
vs.
CEPHALON, INC.,

FILED
APR 23 2008
MICHAEL E. KUNZ, Clerk
Defendant
Dep. Clerk

Filed Under Seal Pursuant to

31 U.S.C. § 3730(b)(2)

JURY TRIAL DEMANDED

SECOND AMENDED
COMPLAINT

CIVIL ACTION NO. 03-6277

HONORABLE THOMAS O'NEILL

On behalf of the United States of America and on behalf of the sovereign states of California, Delaware, Florida, Hawaii, Illinois, Louisiana, Massachusetts, Nevada, New Hampshire, New Mexico, Tennessee, Texas, Virginia and the District of Columbia ("the Certain States") pursuant to the *qui tam* provisions of the Federal False Claims Act, 31 U.S.C. §§ 3729 *et seq.*, (the "FCA"), and the false claims acts of the Certain States (the "state false claims acts"), Plaintiff and Relator Joseph Piacentile, M.D. ("Relator"), files this *qui tam* Complaint against Defendant **CEPHALON, INC.** ("Defendant"). In support thereof, Dr. Piacentile alleges as follows:

INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America and on behalf of the sovereign states of California, Delaware, Florida, Hawaii, Illinois, Louisiana, Massachusetts, Nevada, New Hampshire, New Mexico, Tennessee, Texas, Virginia, and the District of Columbia pursuant to the *qui tam* provisions of the FCA and the

state false claims acts, based on false claims caused to be submitted by Defendant that were and will continue to be submitted to Medicaid and other Government funded health insurance plans in violation of the FCA, and in violation of the state false claims acts.

2. Originally enacted in 1863, the FCA was substantially amended in 1986 by the False Claims Amendments Act. The 1986 amendments enhanced the Government's ability to recover losses sustained as a result of fraud against the United States.

3. The FCA has been interpreted broadly by the Courts, thereby effecting its intent "to reach all types of fraud, without qualification, that might result in financial loss to the Government." *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968).

4. The FCA provides that any person who knowingly submits or causes to be submitted to the Government a false or fraudulent claim for payment or approval is liable for a civil penalty from \$5,500 up to \$11,000 for each such claim, plus three times the amount of the damages sustained by the Government. 31 U.S.C. § 3729.

5. The FCA empowers a private person having information regarding a false or fraudulent claim against the Government to bring an action on the Government's behalf and to share in any recovery. The complaint must be filed under seal without service on the defendant. The complaint remains under seal to give the Government an opportunity to conduct an investigation into the allegations and to determine whether to join the action. 31 U.S.C. § 3730.

6. The state false claims acts are modeled after the FCA and seek to prevent similar harms to state fiscs. *See, e.g.*, the California False Claims Act, Cal. Gov't Code §§ 12650-12655; the Delaware False Claims Act, Del. Code. Ann. tit. 6, § 1201 *et seq.* (2004); the Florida False Claims Act, Fla. Stat. Ann. § 68.081 *et seq.* (2004); the Hawaii False Claims Act, Haw. Rev. Stat. § 661-22 *et seq.* (2004); the Illinois Whistleblower Reward and Protection Act, 740 Ill.

Comp. Stat. 175/1 *et seq.* (2004); the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:439.1 *et seq.* (2004); the Massachusetts False Claims Act, Mass. Ann. Laws ch. 12, § 5(A)-(O) (2004); the Nevada False Claims Act, Nev. Rev. Stat. §357.010 *et seq.* (2004); the New Hampshire Medicaid Fraud and False Claims Law, N.H. Rev. Stat. Ann. § 167:61 *et seq.*; the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-1 *et seq.* (2004); the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.* (2004), and the Tennessee False Claims Act, Tenn. Code Ann. § 4-18-101 *et seq.* (2004); the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. § 36.001 *et seq.* (2004); the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §8.01-216.1 *et seq.* (2004); and the District of Columbia False Claims Act, D.C. Code § 2-308.03 *et seq.* (2004).

7. Pursuant to the FCA and the state false claims acts, relator Joseph Piacentile seeks to recover on behalf of the United States and the Certain States damages and civil penalties arising from the submission of false or fraudulent claims supported by false or misleading statements that Defendant submitted or caused to be submitted to Medicaid and other government funded health insurance programs for payment by the United States and by the Certain States.

8. The Medicaid Program, 42 U.S.C. § 1395, *et seq.*, is administered through the Centers for Medicare and Medicaid Services (“CMS”), which is a division of the Department of Health and Human Service (“HHS”) of the Federal Government. Medicaid is funded by the Federal Government. 42 U.S.C. § 1396. The Federal Government pays a varying percentage of each Medicaid prescription depending on the State. Numerous States limit reimbursement for prescription drugs to those uses approved by the FDA, thereby prohibiting payment for

medications for off-label uses. *See generally United States ex. rel. Franklin v. Parke-Davis*, No. 96-11651, 2003 U.S. Dist. LEXIS 15754, at *9 (D. Mass. Aug. 22, 2003).

9. The FCA, 31 U.S.C. § 3729, provides that:

- (a) Liability for certain acts. Any person who (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government;

* * *

- (7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government, is liable to the United States Government for a civil penalty of not less than \$5,[5]00 and not more than \$1[1],000, plus 3 times the amount of damages which the Government sustains because of the act of that person. . . .

10. As set forth more fully below, defendant Cephalon, Inc. (“Cephalon”), has violated the FCA and other federal statutory and regulatory provisions by promoting the off-label uses of its Gabitril and Provigil prescription pharmaceuticals for the purpose of market expansion.¹ The FDA has only approved Gabitril and Provigil for the treatment of epilepsy and specified sleep disorders, respectively.

11. Cephalon has promoted the off-label uses of Gabitril and Provigil by providing financial incentives to physicians that constitute kickbacks for prescribing and speaking on behalf of non-approved uses of Gabitril and Provigil. Cephalon has also provided benefits to

¹ The Food and Drug Administration (“FDA”) reviews a pharmaceutical manufacturer’s application for approval of a new drug to determine whether the drug’s intended use is safe and effective. 21 U.S.C. § 355. “Off-label” use refers to prescribing that approved drug for a use that has not undergone FDA scrutiny and approval.

other high-prescribing physicians who attend meetings at attractive locations to induce them to prescribe Gabitril and Provigil for off-label purposes. Cephalon has misrepresented the safety and efficacy of the off-label uses of Gabitril and Provigil. Cephalon has caused Medicaid to pay non-reimbursable claims.

12. Cephalon's wrongful conduct has been ongoing from at least 2001 and, on information and belief, likely for years before that. Cephalon's wrongful conduct continues through the present.

13. As a direct consequence of its off-label marketing scheme, Cephalon has caused to be submitted, and the United States and the Certain States have paid, claims that otherwise should not have been reimbursed by Medicaid and other government funded health insurance programs. As a result, the United States and the Certain States have been damaged and continue to be damaged in substantial amounts.

PARTIES

14. Relator Joseph Piacentile, M.D., is a New Jersey physician and businessman. He has conducted an investigation into the wrongdoing by Cephalon.

15. Defendant Cephalon, Inc., is a corporation organized and existing under the laws of Delaware. Cephalon is a pharmaceutical manufacturer with its corporate offices and principal place of business located at 145 Brandywine Parkway, West Chester, Pennsylvania 19380, within the Eastern District of Pennsylvania.

JURISDICTION AND VENUE

16. Relator brings this action on behalf of himself and the United States and the Certain States for violations of the FCA, 31 U.S.C., § 3729 *et seq.*, and the state false claims acts. *See also* The Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*; The Food and Drug Administration and Modernization Act of 1997, 21 U.S.C. § 351 *et seq.*, and 21 U.S.C. § 360aaa

et seq.; the Medicare/Medicaid Fraud & Abuse Anti-Kickback Statute, 42 U.S.C. § 1320a *et seq.*; and Dissemination of Information on Unapproval/New Uses for Marketed Drugs, Biologics, and Devices, 21 C.F.R. § 99.1 *et seq.*

17. The Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732. The latter specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3730, 3732. This Court has supplemental jurisdiction over the counts relating to the state false claims acts pursuant to 28 U.S.C. § 1367.

18. The Court has personal jurisdiction over Defendant pursuant to 31 U.S.C. § 3732(a), which authorizes nationwide service of process, and because Defendant has minimum contacts with the United States.

19. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) because Defendant can be found, resides or transacts, or has transacted, business in the Eastern District of Pennsylvania and/or at least one act proscribed by 31 U.S.C. § 3729 occurred in the Eastern District of Pennsylvania.

BACKGROUND ALLEGATIONS

FDA Regulation of Drugs

20. FDA regulates drugs based on the “intended uses” for such products. A manufacturer who wishes to market any new drug must demonstrate to the FDA that the product is safe and effective for each intended use. *See* 21 U.S.C. § 331(d). *See also* 21 U.S.C. §§ 355(a) and 360b(a).

21. The pharmaceutical manufacturer must provide information not only on how a product is to be used (e.g., dosage and administration), but also on each intended use of the product. 21 C.F.R. § 201.5. The labeling requirements are intended to make drugs safe and effective for all proposed claims. *See generally* 21 C.F.R. §§ 99.1, 201.100(c), (d). A drug shall

be deemed misbranded unless its label bears adequate directions for the approved use. 21 U.S.C. § 352(f)(1).

22. Oral statements and materials presented at industry-supported activities (such as lectures and teleconferences) provide evidence of a product's intended use. If these statements or materials promote a use that is inconsistent with the product's approved labeling, it is misbranded for failure to have labeling with adequate directions for all intended uses. 21 C.F.R. § 99.405.

23. Indeed, dissemination of off-label information by a pharmaceutical company is largely limited to responses to bona fide, unsolicited inquiries. Another exception, though highly circumscribed, is that pharmaceutical companies may disseminate scientific studies investigating off-label use of a product. When doing so, the manufacturer may disseminate only copies of unabridged, peer reviewed scientific and medical articles. The articles must concern drugs that have been approved for other uses by the FDA, and the information must not be false or misleading. 21 C.F.R. § 99.101.

24. Strong policy reasons exist for such strict regulation of off-label marketing. Off-label promotion undercuts the FDA's authority by allowing drug manufacturers to bypass the agency's strict review and approval process. Permitting off-label promotion also removes incentives to obtain definitive clinical study data and weakens the goal of evidence-based medicine.

25. Indeed, allowing unchecked off-label promotion will encourage a pharmaceutical manufacturer to seek FDA approval for the product use easiest to establish. If the pharmaceutical manufacturer knows that it can advertise with impunity, it will likely make its initial application as narrow as possible. The pharmaceutical manufacturer can then conduct

only the minimum clinical trials to gain initial approval for one basic use. The many other uses for which the pharmaceutical manufacturer will actively market the drug will not have been proven safe or effective. The public is put at risk.

26. Cephalon has plainly engaged in just such conduct. Despite the limited indications of Gabitril and Provigil, Cephalon has put inordinate emphasis on their sales. During 2001-2002, Cephalon more than doubled its sales force. 2002 Cephalon Annual Report at 5. Further, Cephalon has stated that "In 2003, we expect to triple our marketing and medical education expenditures to reach out to additional physicians." *Id.* at 11. Cephalon has 760 physicians listed as members of its Speakers Bureau.² The focus on pushing its products is paying off: Since 2001 Gabitril sales have increased 98% and Provigil sales have increased 31%. *Id.* at 11.

27. Cephalon's emphasis on sales is an emphasis on off-label sales. The FDA has only approved Gabitril for epilepsy, but most of its use (reportedly 88%) is for off-label treatment of depression, anxiety, Tourette's Syndrome, chronic pain and other non-seizure conditions. Indeed, a high-prescribing doctor, who is the beneficiary of Cephalon's kickbacks, indicates that of the 400 patients in his practice for whom he has prescribed Gabitril, "none of them" suffer from epilepsy. In other words, all his Gabitril prescriptions are off-label.

² For unclear reasons, Cephalon's Speakers Bureau list includes most but not all the names of the speaker-physicians, although it does typically include their addresses, telephone numbers and (in many cases) e-mail addresses. So, plainly, Cephalon is referring to particular speaker-physicians despite not setting forth their names.

28. Cephalon's Provigil has only been approved for specific sleep disorders, notably narcolepsy,³ which is an "orphan" disease effecting 140,000 Americans. Yet, in 2002, Cephalon reported \$200 million in Provigil sales or nearly half of the company's total revenues. A significant majority (reportedly 80%) of the Provigil sales were off-label.

29. Off-label uses of Provigil have included treatments for adults for chronic fatigue, depression, multiple-sclerosis, Parkinson's disease, anxiety, neuropathic pain and spasticity. The most dangerous off-label use is the treatment of Attention Deficit-Hyperactivity Disorder ("ADHD") in children.

30. Absolutely no FDA approval exists for any of these off-label uses and only a few studies have even considered Provigil for pediatric application.

31. At least one such study is very suspect because the "research" was performed by a high-prescribing and well-compensated Cephalon speaker named Dr. Thomas A. Rugino. More importantly, the study investigated the use of Provigil on only a minuscule group of fifteen children, four of whom were excluded from the final study group. One of the four excluded children developed disorientation and severe tremors and had to be removed from the group.

32. When discussing this study, Cephalon speakers make no mention of this child's reaction to Provigil. Cephalon's conduct is thus false by omission.

33. By the paucity of supporting studies and the omitting of negative information from lectures, Cephalon has placed in jeopardy infant children patients who are being given Provigil by prescriptions written by doctors induced by Cephalon's off-label promotion.

³ The FDA has recently approved an expansion of Provigil's uses to include additional, limited indications for treatment of individuals who suffer from sleep apnea and for individuals who have a difficult time adjusting to night shift work due to sleepiness.

34. Cephalon aggressively sells Provigil as an ADHD treatment drug to make large sums of money and expand the market for the company. Indeed, Cephalon has an entire Provigil program devoted to ADHD treatment. That program is completely off-label.

35. In sum, Cephalon's focused, high-volume, off-label promotion is pernicious to the statutory/regulatory scheme and dangerous to the pediatric patients who receive the drug.

36. Cephalon is no stranger to unlawful off-label marketing that attempts to evade FDA approval procedures. On January 3, 2002, the FDA in a letter to Cephalon's Paul M. Kirsch, Senior Director of Regulatory Affairs, sharply reprimanded Cephalon for its "dissemination of false or misleading [Provigil] promotional materials" in violation of the Food, Drug and Cosmetics Act and applicable regulations. The FDA had reviewed Provigil's promotional materials (sales advertisements, journal advertisements and public website). The FDA disciplined Cephalon for suggesting in those materials that Provigil was safe and effective for a variety of unapproved uses "such as fatigue, tiredness and lack of energy". Indeed, the FDA attached 72 pages of Cephalon promotional materials to its letter, much of which the FDA was highly critical of. The FDA found Cephalon guilty in that it made "misleading" claims "for unapproved uses".

37. In an apparent response to the FDA's reprimand, Cephalon removed that off-label information from its public website. Cephalon, however, has continued to flout the ruling of the FDA by touting physicians to promote off-label uses of Gabitril and Provigil on its password-protected website. On information and belief, Cephalon provides targeted, high-prescribing physicians with passwords to access that off-labeling information on its website. In other words, the goal of off-label promotion is the same. Cephalon has simply re-directed its strategy to keep it away from the FDA's regulatory oversight.

Legitimate CME Programs

38. To be sure, physicians are permitted to attend legitimate continuing medical education (“CME”) events put on by accredited providers. The Accreditation Council for Continuing Medical Education (“ACCME”) has promulgated the Standards for Commercial Support of Continuing Medical Education. Commercial organizations, such as pharmaceutical manufacturer Cephalon, may provide educational grant money for “educational” events to CME accredited providers.

39. However, under the ACCME Standards, the accredited provider is solely responsible for “the content, quality and scientific integrity” of the CME activities. The accredited provider - not the pharmaceutical company - determines program “content, faculty, educational methods and materials.” The CME program must be “free of commercial bias for ... any product.” Any discussion of off-label use must make clear that those drugs are not FDA-approved for such purposes. Faculty members cannot be paid by the grant-giving pharmaceutical company. Any financial interest of the faculty members and the grant-giving pharmaceutical company must be disclosed.

40. As clear from the discussion below, none of the Cephalon activities discussed below can be characterized as legitimate CME activities.

SPECIFIC ALLEGATIONS

41. Defendant has improperly promoted the off-label use of Cephalon drugs, which resulted in improper billings to Medicaid seeking reimbursement from the United States and the Certain States.

42. A pharmaceutical manufacturer or other entity cannot provide financial incentives to a physician that may undermine his/her medical judgment in prescribing drugs. *See* 42 U.S.C. § 1395nn (a)(1), (h)(6); 42 U.S.C. § 1320a-7a(a)(5); 1320a-7b(b) (the Medicare Fraud &

Abuse/Anti-Kickback Statute, which also covers kickbacks affecting the Medicaid program). Nor may a pharmaceutical manufacturer or other entity promote a drug inconsistent with its approved use where the promotion is untruthful regarding the safety and efficacy of the drug. 21 U.S.C. § 331. Nor may a pharmaceutical manufacturer promote off-label use that causes non-reimbursable claims to be presented to Medicaid for payment. *See also* 42 U.S.C. § 1395(a)(1), (g)(1).

43. Despite those proscriptions and the FDA's very limited approvals of Gabitril and Provigil, Defendant has promoted broad off-label usage of these drugs in violation of the FCA. Without limitation, Defendant has done so in the following ways:

A. Kickbacks

44. Cephalon has provided monetary incentives to doctors who are high-prescribers of Gabitril and Provigil by paying lucrative fees to them for speaking at lectures, dinner meetings and teleconferences. One such high-prescribing physician and prolific Cephalon speaker stated that Cephalon pays him \$1,500 per lecture, more than other drug companies. He estimated that he speaks 3 to 4 nights per week and does "a lot for Cephalon."

45. The lucrative speaking fees are remuneration for past high-prescribing and inducements to write future prescriptions for off-label use of Cephalon products. In the words of the same physician, "If you don't pump the numbers, then [the drug companies like Cephalon] are not gonna be that interested in [you]. . . . I'm a high prescriber and I give a good lecture." (This is the same physician with 400 patients on Gabitril, none with the FDA approved indication of epilepsy.) The benefits are also inducements to influence the high-prescribing speakers to tout the off-label uses of Cephalon products to audiences of influential physicians.

46. Cephalon targets such influential doctors to be attendees of lectures. The lectures typically take place at attractive locations. One such weekend event on June 21-23, 2002, was at the Four Seasons Aviara, "a deluxe resort" near San Diego. Cephalon paid for the travel, hotel and meal expenses of the attendees. Cephalon also paid for leisure activities such as golf, tennis lessons, sightseeing, spa treatments and deep sea fishing. As the San Diego "Provigil Consultants Meeting" suggests, these events are in reality little more than paid vacations for high-prescribing physicians to speak on or to receive Cephalon's promotional messages regarding the off-label uses of Gabitril and Provigil.

47. To the same end, Cephalon also holds smaller programs involving dinners at high-end restaurants. Similarly, Cephalon organizes teleconferences where invitees may be paid, purportedly, for their time.

48. For all these events, Cephalon is engaging in direct marketing often under the guise of presenting legitimate, independent CME programs. Dates, times, faculty and locations are all suggested by Cephalon. Cephalon participates in the audience selection to get 70-80% of its target group. Cephalon representatives help deliver invitations. Cephalon slides are used. The Cephalon speakers invariably move into telling how they really use Gabitril and Provigil—off-label. That is the purpose of the lectures, dinners and teleconferences.

49. Federal statutory and regulatory law prohibits kickbacks for the promotion of off-label drug usage. A pharmaceutical manufacturer or other entity may not offer remuneration in any form to a beneficiary that the company knows or should know is likely to influence the beneficiary to prescribe items from a particular supplier. 42 U.S.C. § 1320a-7a(a)(5); § 1320a-7b(b) (the Medicare Fraud & Abuse/Anti-Kickback Statute, which also covers kickbacks affecting the Medicaid program).

50. Kickbacks have the effect of reducing a patient's healthcare choices as unscrupulous physicians steer the patient to off-label products based on the physician's own financial interests, rather than the patient's medical needs. More basically, kickbacks undermine the physician's medical judgment as to the appropriate drug to prescribe.

B. Stark Law Violations

51. The Medicare/Medicaid Self-referral Statute is commonly known as the "Stark" law. It prohibits a pharmaceutical manufacturer from paying remuneration to physicians for referring Medicaid patients to the manufacturer for certain "designated health services," including drug prescriptions where the referring physician has a nonexempt "financial relationship" with the manufacturer. 42 U.S.C. § 1395nn(a)(1), (h)(6). Stark provides that the manufacturer shall not cause to be presented a Medicaid claim for such prescriptions. Stark prohibits payment of Medicaid claims for prescriptions rendered in violation of its provisions, 42 U.S.C. § 1395nn(a)(1), (g)(1).

52. Here, Cephalon provided significant incentives in the form of lucrative and frequent speaking fees to doctors who were high-prescribers (who "pump the numbers") of Gabitril and Provigil. The fees rewarded the doctors for referring patients to Cephalon's products and for advocating such referrals to other physicians. Under the Stark law, Cephalon should not have been providing remuneration and incentives for those referrals. Further, through events like expense-paid weekend vacations and dinners at high-end restaurants, Cephalon seeks to induce influential doctors to prescribe off-label uses of Gabitril and Provigil. *See ¶¶ 48-52, supra.*

C. Misrepresentations

53. Cephalon had previously done off-label marketing on its public website (along with off-label advertising in periodicals). Cephalon apparently shifted strategy after being reprimanded by the FDA in January 2002. Now Cephalon has posted on its password-protected website off-label information available to targeted physicians. Cephalon has provided its speakers with materials promoting the off-label uses of Gabitril and Provigil for the purpose of market expansion.

54. That off-label information is false or misleading regarding the safety and efficacy of Gabitril and Provigil. At its lectures, dinners and teleconferences, Cephalon has incompletely described the potential adverse effects of those drugs when used off-label.

55. For instance, Provigil speakers on the off-label uses for ADHD employ professional slide presentations designed and prepared by Cephalon. The slides note some side effects but falsely omit that use could result in dizziness, depression and tremors along with other conditions. Provigil speakers also falsely omit from lectures the disorientation and severe tremors suffered by one child in a small Provigil study. *See ¶¶ 33-37, supra.*

56. Regarding the efficacy of Provigil for the off-label treatment of ADHD, one Cephalon speaker has privately acknowledged that Provigil would “never be a first line drug” for ADHD. Because of the powerful incentives provided by Cephalon’s illegal remuneration, that speaker does not impart his view of Provigil’s limited effectiveness to the audiences at lectures funded by Cephalon. Cephalon’s illegal largesse undermines the independence and accuracy of the information being provided to its hand-picked audience.

57. The Cephalon-compensated speakers direct their off-label messages at the targeted audience of high-prescribing and influential physicians, who are induced by expense-

paid weekends, dinners at high-end restaurants and purported reimbursement for time spent on teleconferences. Cephalon intends that those audiences be made receptive to the Cephalon message that Gabitril and Provigil can and should be used off-label. Market expansion is served.

D. Non-reimbursable Claims

58. Numerous States prohibit the submission of claims for medication for off-label uses. Through its promotion of off-label usage, Defendant has wrongly caused to be presented non-reimbursable claims to Medicaid and other government funded health insurance programs for payment by the Federal Government and by the Certain States. *See ¶¶ 8, 46, 58-59, and 61-66, supra. See generally United States ex. rel. Franklin v. Parke-Davis*, No. 96-11651, 2003 U.S. Dist. LEXIS 15754, at *9 (D. Mass. Aug. 22, 2003).

COUNT ONE

False Claims Act, 31 U.S.C. § 3729(a)(1)

59. Relator re-alleges and incorporates by reference the allegations contained in Paragraphs 1 through 58 of this complaint.

60. This is a claim for treble damages and civil penalties under the False Claims Act, 31 U.S.C. § 3729 (a)(1).

61. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the United States Government false or fraudulent claims for the payment or approval of prescriptions for improper off-label uses of Cephalon products.

62. The United States and the Certain States, unaware of the falsity or fraudulent nature of the claims that Defendant caused, paid for claims that would otherwise not have been allowed.

63. By reason of these payments, the United States and the Certain States have been damaged, and continue to be damaged in substantial amounts.

COUNT TWO

False Claims Act, 31 U.S.C. § 3729(a)(2)

64. Relator re-alleges and incorporates by reference the allegations contained in Paragraphs 1 through 58 of this complaint.

65. This is a claim for treble damages and civil penalties under the False Claims Act, 31 U.S.C. § 3729 (a)(2).

66. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendant knowingly made, used or caused to be made or used false records or statements to cause false or fraudulent claims to be paid or approved by the United States Government.

67. The United States, unaware of the falsity or fraudulent nature of the claims that Defendant caused, paid for claims that would otherwise not have been allowed.

68. By reason of these payments, the United States has been damaged, and continues to be damaged in a substantial amount.

COUNT THREE

California False Claims Act, Cal. Gov't Code § 12651 *et seq.*

69. Relator re-alleges and incorporates by reference the allegations made in Paragraphs 1 through 58 of this complaint.

70. This is a claim for treble damages and civil penalties under the California False Claims Act. Cal. Gov't Code § 12651 *et seq.*

71. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the

California Medicaid Program (*i.e.*, Medi-Cal) false or fraudulent claims for the improper payment or approval of prescriptions for off-label uses of Gabitril and Provigil, and used false records to accomplish this purpose.

72. The California Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

73. By reason of these payments, the California Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT FOUR

Delaware False Claims Act, Del. Code Ann. tit. 6, § 1201 *et seq.*

74. Relator re-alleges and incorporates by reference the allegations made in Paragraphs 1 through 58 of this complaint.

75. This is a claim for treble damages and civil penalties under the Delaware False Claims Act. Del Code Ann. tit. 6, § 1201 *et seq.*

76. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Delaware Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for off-label uses of Gabitril and Provigil, and used false records to accomplish this purpose.

77. The Delaware Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

78. By reason of these payments, the Delaware Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT FIVE

Florida False Claims Act, Fla. Stat. Ann. § 68.081 *et seq.*

79. Relator re-alleges and incorporates by reference the allegations made in Paragraphs 1 through 58 of this complaint.

80. This is a claim for treble damages and civil penalties under the Florida False Claims Act. Fla. Stat. Ann. § 68.081 *et seq.*

81. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Florida Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for off-label uses of Gabitril and Provigil, and used false records to accomplish this purpose.

82. The Florida Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

83. By reason of these payments, the Florida Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT SIX

Hawaii False Claims Act, Haw. Rev. Stat. § 661-22 *et seq.*

84. Relator re-alleges and incorporates by reference the allegations made in Paragraphs 1 through 58 of this complaint.

85. This is a claim for treble damages and civil penalties under the Hawaii False Claims Act. Haw. Rev. Stat. § 661-22 *et seq.*

86. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Hawaii Medicaid Program false or fraudulent claims for the improper payment or approval of

prescriptions for off-label uses of Gabitril and Provigil, and used false records to accomplish this purpose.

87. The Hawaii Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

88. By reason of these payments, the Hawaii Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT SEVEN

Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. 175/1 et seq.

89. Relator re-alleges and incorporates by reference the allegations made in Paragraphs 1 through 58 of this complaint.

90. This is a claim for treble damages and civil penalties under the Illinois Whistleblower Reward and Protection Act. 740 Ill. Comp. Stat. 175/1 *et seq.*

91. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Illinois Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for off-label uses of Gabitril and Provigil, and used false records to accomplish this purpose.

92. The Illinois Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

93. By reason of these payments, the Illinois Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT EIGHT

Louisiana Medical Assistance Programs Integrity Law,

La. Rev. Stat. Ann. § 46:439.1 et seq.

94. Relator re-alleges and incorporates by reference the allegations made in Paragraphs 1 through 58 of this complaint.

95. This is a claim for treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law. La. Rev. Stat. Ann. § 46:439.1 *et seq.*

96. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Louisiana Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for off-label uses of Gabitril and Provigil, and used false records to accomplish this purpose.

97. The Louisiana Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

98. By reason of these payments, the Louisiana Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT NINE

Massachusetts False Claims Act, Mass. Ann. Laws ch. 12, § 5(A)-(O)

99. Relator re-alleges and incorporates by reference the allegations made in Paragraphs 1 through 58 of this complaint.

100. This is a claim for treble damages and civil penalties under the Massachusetts False Claims Act. Mass. Ann. Laws ch. 12, § 5(A)-(O).

101. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the

Massachusetts Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for off-label uses of Gabitril and Provigil, and used false records to accomplish this purpose.

102. The Massachusetts Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

103. By reason of these payments, the Massachusetts Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT TEN

Nevada False Claims Act, Nev. Rev. Stat. §357.010 *et seq.*

104. Relator re-alleges and incorporates by reference the allegations made in Paragraphs 1 through 58 of this complaint.

105. This is a claim for treble damages and civil penalties under the Nevada False Claims Act. Nev. Rev. Stat. §357.010 *et seq.*

106. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Nevada Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for off-label uses of Gabitril and Provigil, and used false records to accomplish this purpose.

107. The Nevada Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

108. By reason of these payments, the Nevada Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT ELEVEN

New Hampshire Medicaid Fraud and False Claims, N.H. Rev. Stat. Ann. § 167:61, et seq.

109. Relator re-alleges and incorporates by reference the allegations made in Paragraphs 1 through 58 of this complaint.

110. This is a claim for treble damages and civil penalties under the New Hampshire Medicaid Fraud and False Claims Law, N.H. Rev. Stat. Ann. § 167:61, *et seq.*

111. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the New Hampshire Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for off-label uses of Gabitril and Provigil, and used false records to accomplish this purpose.

112. The New Hampshire Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

113. By reason of these payments, the New Hampshire Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT TWELVE

New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-1 et seq.

114. Relator re-alleges and incorporates by reference the allegations made in Paragraphs 1 through 58 of this complaint.

115. This is a claim for treble damages and civil penalties under the New Mexico Medicaid False Claims Act. N.M. Stat. Ann. § 27-14-1 *et seq.*

116. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the New

Mexico Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for off-label uses of Gabitril and Provigil, and used false records to accomplish this purpose.

117. The New Mexico Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

118. By reason of these payments, the New Mexico Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT THIRTEEN

Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.*

Tennessee False Claims Act, Tenn. Code Ann. § 4-18-101 *et seq.*

119. Relator re-alleges and incorporates by reference the allegations made in Paragraphs 1 through 58 of this complaint.

120. This is a claim for treble damages and civil penalties under the Tennessee Medicaid False Claims Act, and Tennessee False Claims Act. Tenn. Code Ann. § 71-5-181 *et seq.*; Tenn. Code Ann. § 4-18-101 *et seq.*

121. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Tennessee Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for off-label uses of Gabitril and Provigil, and used false records to accomplish this purpose.

122. The Tennessee Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

123. By reason of these payments, the Tennessee Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT FOURTEEN

Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. § 36.001 *et seq.*

124. Relator re-alleges and incorporates by reference the allegations made in Paragraphs 1 through 58 of this complaint.

125. This is a claim for treble damages and civil penalties under the Texas Medicaid Fraud Prevention Act. Tex. Hum. Res. Code Ann. § 36.001 *et seq.*

126. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Texas Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for off-label uses of Gabitril and Provigil, and used false records to accomplish this purpose.

127. The Texas Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

128. By reason of these payments, the Texas Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT FIFTEEN

Virginia Fraud Against Taxpayers Act, Va. Code Ann. §8.01-216 *et seq.*

129. Relator re-alleges and incorporates by reference the allegations made in Paragraphs 1 through 58 of this complaint.

130. This is a claim for treble damages and civil penalties under the Virginia Fraud Against Taxpayers Act. Va. Code Ann. §8.01-216 *et seq.*

131. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Virginia Medicaid Program false or fraudulent claims for the improper payment or approval of

prescriptions for off-label uses of Gabitril and Provigil, and used false records to accomplish this purpose.

132. The Virginia Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

133. By reason of these payments, the Virginia Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT SIXTEEN

District of Columbia False Claims Act, D.C. Code § 2-308.03 et seq.

134. Relator re-alleges and incorporates by reference the allegations made in Paragraphs 1 through 58 of this complaint.

135. This is a claim for treble damages and civil penalties under the District of Columbia False Claims Act. D.C. Code § 2-308.03 *et seq.*

136. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the District of Columbia Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for off-label uses of Gabitril and Provigil, and used false records to accomplish this purpose.

137. The District of Columbia Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

138. By reason of these payments, the District of Columbia Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

WHEREFORE, Relator Joseph Piacentile requests that judgment be entered against Defendant, ordering that:

- a. Defendant cease and desist from violating the False Claims Act, 31 U.S.C. § 3729, *et seq.*, and the state false claims acts;
- b. Defendant pay not less than \$5,500 and not more than \$11,000 for each violation of 31 U.S.C. § 3729, plus three times the amount of damages the United States has sustained because of Defendant's actions, plus the appropriate amount to the Certain States under similar provisions of the state false claims acts;
- c. Relator be awarded the maximum "relator's share" allowed pursuant to 31 U.S.C. § 3730(d) and similar provisions of the state false claims acts;
- d. Relator be awarded all costs of this action, including attorneys' fees and costs pursuant to 31 U.S.C. § 3730(d) and similar provisions of the state false claims acts;
- e. Defendant be enjoined from concealing, removing, encumbering or disposing of assets which may be required to pay the civil monetary penalties imposed by the Court;
- f. Defendant disgorge all sums by which it has been enriched unjustly by its wrongful conduct; and
- g. The United States and relator Joseph Piacentile recover such other relief as the Court deems just and proper.

REQUEST FOR TRIAL BY JURY

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, relator Joseph Piacentile hereby demands a trial by jury.

Dated: April 18, 2008

Respectfully submitted,

By: _____ /s/

Robert A. Magnanini (Bar No. 70630)
David S. Stone
BOIES, SCHILLER & FLEXNER LLP
150 John F. Kennedy Parkway
4th Floor
Short Hills, NJ 07078
973-218-1111

COUNSEL FOR RELATOR JOSEPH PIACENTILE

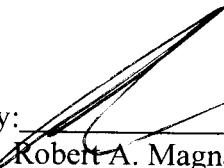
REQUEST FOR TRIAL BY JURY

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, relator Joseph Piacentile hereby demands a trial by jury.

Dated: April 18, 2008

Respectfully submitted,

By:


Robert A. Magnanini (Bar No. 70630)
David S. Stone
BOIES, SCHILLER & FLEXNER LLP
150 John F. Kennedy Parkway
4th Floor
Short Hills, NJ 07078
973-218-1111

COUNSEL FOR RELATOR JOSEPH PIACENTILE

